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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,971	02/02/2001	John D. Shaughnessy	D6138	3345

7590 10/20/2004
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/778,971	Applicant(s) SHAUGHNESSY, JOHN D.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Shaughnessy J.D.
Priority Date: 4 February 2000

1. Upon further search and reconsideration, the finality of the instant application is withdrawn.
2. Applicant's submission of the appeal brief filed 4/26/2004 is acknowledged and entered into the record.
3. Claims 1, 5-21 are pending, claims 2-4 are canceled without prejudice or disclaimer, claims 9-21 are withdrawn as being drawn to a non-elected invention.
4. Claims 1 and 5-8 are therefore examined on the merits.

Claim Rejections Maintained - 35 USC § 101

5. The rejection of claims 1 and 5-8 under 35 USC 101 as lacking a credible, substantial, and specific utility is maintained for the reasons of record. Applicant's arguments submitted 4/26/2004 in the appeal brief are substantially similar to those previously presented in filings on 8/11/2003, 1/20/2004, and 2/25/2004. Since no new arguments have been presented, the reasons set forth in previous office actions are hereby maintained.

New Arguments

Claim Rejections - 35 USC § 112, 2nd paragraph

6. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 5 recites an isolated genomic DNA encoding the IL-17 receptor-related protein, wherein the genomic DNA comprises the coding sequence that are identical to the nucleic acid of SEQ ID No: 1. Because the genomic DNA comprises both introns and exons, it cannot comprise within it a sequence that is identical to SEQ ID No: 1. The specification teaches that SEQ ID No: 1 is a cDNA molecule that essentially represents the exons of the genomic DNA molecule. Moreover, because the claim is interpreted as being "open", the metes and bounds of the term cannot be adequately determined. Essentially the genomic DNA claimed comprises the entire chromosome on which the locus of Evi27 is located.

Claim Rejections - 35 USC § 112, 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth the sequence of SEQ ID No: 1 and therefore the written description is not commensurate in scope to the claim that reads on genomic DNA comprising the sequence of SEQ ID No: 1.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The specification of the instant application fails to provide essential structural information regarding the critical features of the genomic DNA claimed. Because the claim is interpreted with open language, the claimed genomic DNA encompasses more than sequences that are identical to the coding regions of SEQ ID No: 1. The specification has not provided sequences that represent introns, promoters, enhancers, poly A signals, terminators, and other “genes” that are present within the genomic DNA claimed. The art indicates that the structures of genes with naturally occurring regulatory elements and untranslated regions is empirically determined (Harris et al., J. of The Am Society of Nephrology 6:1125-33, 1995; Ahn et al., Nature Genetics 3(4):283-91, 1993; and Cawthon et al., Genomics 9(3):446-60, 1991). Therefore, the structure of these elements is not conventional in the art, and one skilled in the art would therefore not recognize from the disclosure that applicant was in possession of the genus of “genomic DNA” claimed. Furthermore, as stated above, the open

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language encompasses more than the coding regions that make up SEQ ID No: 1, and can be interpreted as encompassing the entire chromosome on which Evi 27 resides.

Although drawn specifically to the DNA art, the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Therefore, only SEQ ID No: 1 and not the breadth of "genomic DNA" has meet the requirements of written description under 35 USC 112, 1st paragraph.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Copeland *et al* (Science. 1993 Oct 1;262(5130):57-66). The specification of the instant invention

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states that Copeland *et al* teach "that Evi27 maps to mouse chromosome 14 in a region of human 3p21 homology". Therefore because the claim is interpreted as being open because of the comprising language, for the purposes of this rejection, a chromosome on which Evi27 is found anticipates the instant claims to a genomic DNA.

Conclusion

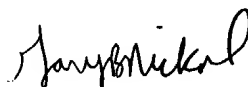
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
July 1, 2004



**GARY B. NICKOL, PH.D.
PRIMARY EXAMINER**